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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,454	09/17/2003	Mark L. Jenson	760-68	4333
23869 7590 01/31/2008 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER SCHILLINGER, ANN M	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 01/31/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/664,454

Applicant(s)

JENSON, MARK L.

Examiner

Ann Schillinger

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11, 13-16, 18-21, 27, and 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Rudakov et al. (US Pat. No. 6,451,050). Rudakov et al. discloses the following of claim 1: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (12); a second polymeric liner (13; col. 2, lines 11-13); an intermediate structural member (16, 17) interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments and openings (col. 2, lines 1-7, 31-64) therebetween such that the first liner is bonded to the second liner through said openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners and said solid segments (see Figures 2, 3); and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 4, lines 36-66).

Rudakov et al. discloses the limitations of claims 2-8 as shown in Figures 2 and 3.

Rudakov et al. discloses the limitations of claim 9 in col. 4, lines 36-49.

Rudakov et al. discloses the limitations of claims 10, 19, and 20 in col. 2, lines 31-34, 55-58. Please note that the examiner is interpreting the limitation "foreign" to be any substance viewed as foreign relative to the human body.

Rudakov et al. discloses the limitations of claim 11 in col. 4, lines 41-43.

Rudakov et al. discloses the limitations of claims 13-16, 18 and 21 in col. 9, lines 9-21.

Rudakov et al. discloses the following of claim 27: a composite intraluminal device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: an elongate stent (16, 17) having a generally cylindrical tubular body defined by solid segments and openings between said solid segments, said tubular body defining an inner surface and an opposed outer surface (see Figures 2, 3; col. 2, lines 1-7, 31-64); a first polymeric liner (12) positioned about said inner surface of said tubular body; a second polymeric liner (13) positioned about said outer surface of said tubular body; said second polymeric liner being joined to said first liner through said stent openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners and said solid segments (SEE Figures 2, 3); and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said tubular body (col. 4, lines 36-66).

Rudakov et al. discloses the limitations of claims 48-51 in col. 4, lines 36-41.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al. in view of Helmus et al. (US Pub. No. 2002/0032477). Rudakov et al. discloses the invention substantially as claimed, however, Rudakov et al. does not disclose constructing the polymeric matrix holding the bioactive agent of microparticles. Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix in paragraph 0048 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al. in view of Buirge et al. (US Pat. No. 5,693,085). Rudakov et al. discloses the invention substantially as claimed, however, Rudakov et al. does not disclose using a natural polymer to comprise the liners. Buirge et al. teaches a biological stent using a natural polymer, collagen, in col. 3, line 31 through col. 4, line 5; col. 6, lines 11-16 for the purpose of utilizing the collagen's biological protection during cellular regrowth. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a natural polymer in order to utilize the polymer's biological protection during cellular regrowth.

Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al. in view of Lentz et al. (U.S. Patent No. 6,428,571). Rudakov et al. discloses the invention substantially as claimed, but it does not disclose the liners having different porosities. Lentz et al. teaches a vascular graft with liners having different porosities in col. 3, lines 1-35; col. 4, lines 24-48 for the purpose of allowing one layer to promote cell endothelization, while the other layer

has a higher degree of radial strength. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use internodal distances less than 40 microns for radial strength and greater than 40 microns for long term patency.

***Response to Arguments***

Applicant's arguments filed 11/16/2007 have been fully considered but they are not persuasive. Regarding the Rudakov et al. reference, openings exist between elements 16 as shown in Figures 6 and 7. The first and second liners are bonded together within that space via element 17. The claim language does not state that the two layers must be bonded directly to one another, thus leaving the claim open to be interpreted as potentially having another element available to secure a bond between the polymeric layers.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Application/Control Number:  
10/664,454  
Art Unit: 3774


Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger  
January 28, 2008

  
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